IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC Plaintiffs, v. BARR LABORATORIES, INC. Defendants.	C.A. No. 06-286-GMS

JOINT STATUS REPORT

Pursuant to Rule 16, Fed. R. Civ. P., D. Del. LR 16.2, and the Court's Notice of Scheduling Conference, the parties, by and through their undersigned counsel, jointly submit this Status Report. Counsel for the parties participated in a telephone conference pursuant to the Notice of Scheduling Conference and as required by Fed. R. Civ. P. 26(f) on July 6, 2006. Joshua R. Rich and Jeremy E. Noe of McDonnell, Boehnen, Hulbert, and Berghoff LLP participated via telephone on behalf of the plaintiffs, and Maureen L. Rurka and Julia M. Mano of Winston & Strawn LLP participated via telephone on behalf of the defendant.

I. Joint Status Report

1. Jurisdiction and Service:

The parties agree that the Court has subject-matter jurisdiction over Plaintiffs' claims and Defendant's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) to the extent that the subject matter relates solely to 35 U.S.C. § 271(e)(2). The parties further agree that the Court has personal jurisdiction over each of the parties. Plaintiffs dispute whether the Court has jurisdiction over the subject matter of any counterclaim that encompasses acts of infringement beyond 35 U.S.C. § 271(e)(2). Defendant disputes whether Co-Plaintiff Sanofi-Aventis U.S. LLC has standing under 35 U.S.C. § 281 to sue for infringement of the '573 and '329 patents. No parties remain to be served.

2. Substance of the Action:

Plaintiffs state that they sell drug products containing triamcinolone acetonide in the United States under the Trademark NASACORT AQ®, pursuant to NDA 20-468 held by Sanofi-Aventis US LLC. Plaintiffs allege that use of these drug products is covered by United States Patent Nos. 5,976,573 ("the '573 patent") and 6,143,329 ("the '329 patent"), both of which have been owned at all times by Aventis or one of its predecessors-in-interest. Plaintiffs allege that Defendant's submission of ANDA 78-104 constitutes infringement of one or more of the claims of the '573 and '329 patents. Plaintiffs further allege Defendant's infringement is willful, and that they will be substantially and irreparably harmed by Defendant's infringement.

Defendant states that it filed ANDA No. 78-104 with the FDA seeking generic approval for triamcinolone acetonide aqueous nasal spray, 0.055 µg/spray. Defendant's ANDA includes paragraph IV certifications to the '573 and '329 patents. Defendant sent Plaintiffs a statutorily-

required notice letter of its paragraph IV certifications on March 20, 2006. Defendant denies that it has infringed or would infringe claims of the '573 and '329 patents through the manufacture, use or sale of its proposed ANDA product. Defendant also denies that submission of its ANDA constitutes willful infringement of the '573 and '329 patents. Defendant further contends that the claims of the '573 and '329 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

3. Identification of Issues:

In addition to the disputed issues discussed elsewhere relating to subject matter jurisdiction, dismissal or bifurcation of Plaintiffs' willful infringement claims, and Defendant's jury demand, the factual and legal issues genuinely in dispute are: (1) whether the manufacture, use and/or sale of Defendant's proposed ANDA product would infringe the '573 and '329 patents, (2) whether Defendant has willfully infringed the '573 and '329 patents, and (3) whether the '573 and '329 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

4. Narrowing of Issues:

Presently pending before the Court is Defendant's motion to dismiss Plaintiffs' willful infringement claims. The parties expect that, as discovery proceeds and the case progresses, they may be able to narrow the issues by way of stipulation or dispositive motions.

5. Relief:

Plaintiffs seek: (1) a judgment declaring that Defendant has infringed, and that the making, using, selling, offering to sell or importing of the ANDA product would infringe the '573 patent and the '329 patent; (2) a judgment providing that the effective date of any FDA approval for Defendant to make, use or sell the ANDA product be no earlier than the later of the dates on which the '573 and '329 patents expire; (3) a preliminary and permanent injunction prohibiting the making, using, selling, offering to sell, or importing of the ANDA product until after both the '573 and the '329 patents have expired; (4) if Defendant engages in the commercial manufacture, use or sale of its ANDA product prior to expiration of the '573 patent or the '329 patent, a judgment awarding Plaintiff actual damages resulting from such infringement, increased to treble the amount found or assessed, together with interest; (5) an award of attorney fees, costs, and expenses in this action under 35 U.S.C. § 285; and (6) an award of any further and additional relief as the Court deems just and proper. Plaintiffs further state that they are unable to calculate an exact monetary demand without discovery.

Defendant seeks a judgment and order (1) declaring that the claims of the '573 and '329 patents are invalid; (2) declaring that Defendant has not infringed and that its manufacture, use, or sale of products covered by ANDA No. 78-104 would not infringe the claims of the '573 and '329 patents; (3) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendant its attorney fees, costs, and expenses in this action; and (4) awarding Defendant any further and additional relief as the Court deems just and proper.

6. Amendment of Pleadings:

The parties cannot yet assess the likelihood that they will need to seek to amend the pleadings in this action, but they respectfully seek to reserve the right to file motions to amend the pleadings within the deadlines set forth in the proposed dates.

7. Joinder of Parties:

The parties cannot yet assess the likelihood that they will need to seek to join parties in this action, but they respectfully seek to reserve the right to file motions to join parties within the deadlines set forth in the proposed dates.

8. Discovery:

Please see the following chart for the parties' joint proposed deadlines in the case. In addition, the parties agree to be governed by the provisions of the Federal Rules of Civil Procedure with respect to limits on discovery, except they agree, subject to the Court's approval, that each side should be permitted to serve a total of 50 interrogatories, including all discrete subparts, upon the opposing party, and that each side should be permitted to take 10 depositions of the opposing party.

Deadline	Joint Proposal
Initial Disclosures	August 15, 2006
Join Parties/Amend Pleadings	December 15, 2006
Fact Discovery Cutoff	July 6, 2007
Opening Expert Reports	August 10, 2007
Rebuttal Expert Reports	September 14, 2007
Expert Discovery Cutoff	November 2, 2007
Opening Dispositive Motions	November 30, 2007
Opposition to Dispositive Motions	December 21, 2007
Replies to Dispositive Motions	January 11, 2007
Pretrial Order	February 22, 2008
Pretrial Conference	March 2008
Trial	April 2008

9. Estimated Trial Length:

The parties estimate that, while the extent of many issues are not yet known as no discovery has been conducted, the trial should take approximately three to five days. Defendant contends that bifurcation of Plaintiffs' willful infringement claims is appropriate in the event those claims are not dismissed. Plaintiffs disagree and contend that bifurcation of their willful infringement claims is not appropriate.

10. Jury trial:

Defendant's answer and counterclaims include a jury demand. Defendant's current intention is to request a trial by jury. Plaintiffs contend Defendant's jury demand on declaratory judgment counterclaims is inappropriate in an ANDA action as a matter of law, and that this issue is best resolved via motion under Rule 39 at a time to be determined by the Court.

11. Settlement:

The parties agree that mediation would appear not to provide beneficial resolution to this action and that the possibility of reaching settlement is remote.

12. Other matters:

The parties agree that a protective order will be necessary due to confidential business information that will need to be exchanged in this action. The parties expect to present a stipulated protective order to the Court for its consideration.

13. Counsel for the parties have conferred about each of the above matters.

Respectfully submitted,

ASHBY & GEDDES

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